UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH DAKOTA
WESTERN DIVISION

MARK A. ERK and CANDACE R. ERK MANTHEY, Plaintiffs, vs. BAYER CORPORATION; an Indiana corporation, a wholly owned subsidiary of BAYER AG; BAYER AG, a German corporation; SMITHKLINE BEECHAM CORPORATION, d/b/a GLAXOSMITHKLINE, a Pennsylvania corporation, Defendants.	C 03-5075 **COMPLAINT**

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UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: BAYCOL PRODUCTS LITIGATION	MDL NO. 1431 (MJD/JGL)

COMES NOW the plaintiffs, MARK A. ERK and CANDACE R. ERK MANTHEY, husband and wife, and for their cause of action state and allege as follows:

MDL
CONSOLIDATION OF RELATED ACTIONS

1. Pursuant to Court Order No. 1, dated January 16, 2002, all cases in Federal Court that relate to Baycol Products Litigation are consolidated in United States District Court, District of Minnesota, MDL No. 1431, In re: Baycol Products Litigation.

PARTIES

2. Plaintiffs are residents of Rapid City, SD. Plaintiff Mark Erk (Plaintiff Erk) was prescribed, purchased and ingested 0.3 mg of Baycol each day from September 11, 1998, until April 6, 1999, when the dosage was increased to 0.6 mg daily. On September 7, 1999, Plaintiff Erk presented to the doctor with severe, diffuse body aches (muscles and joints) and weakness which had started approximately three days prior to September 7, 1999. He had discontinued the Baycol a couple of days before seeking medical treatment because of the severe muscle pain and weakness. CPK results were initially 400, but dramatically increased on September 9, 1999, to 3300.

3. Plaintiffs have a cause of action against the Defendants for the pain, suffering, and medical expenses incurred by Plaintiffs, which expenses were proximately caused by the negligence and conduct of the Defendants, including the reckless disregard of Plaintiffs' rights by the Defendants.

4. Defendant Bayer Corporation is a corporation of the state of Indiana, with its principal place of business in Pittsburgh, Pennsylvania. It is a wholly owned subsidiary of Defendant Bayer AG. At all times relevant herein, Bayer Corporation was in the business of promoting, manufacturing and distributing certain pharmaceutical products, including a certain cerivastatin sodium medication known as Baycol. Additionally, at all times relevant hereto, Bayer Corporation and Bayer AG shared many of the same officers and directors. Defendant Bayer Corporation does business in South Dakota and at all times material hereto marketed, promoted, warranted and sold its products, including Baycol, in South Dakota. Hereinafter Bayer Corporation and Bayer AG may be collectively referred to as the "Bayer Defendants."

Bayer Corporation has sufficient contacts with the state of South Dakota for purposes of proper service and personal jurisdiction.

5. Defendant Bayer AG, a global diversified chemical company, is a German corporation, with its principal place of business in Leverkusen, Germany. The research, development, formulation, manufacture, marketing and sales of pharmaceuticals, including Baycol, comprise more than 30% of Bayer AG's worldwide business. At all times relevant herein, Bayer AG was in the business of designing, testing, manufacturing, distributing and promoting certain pharmaceutical products, including a certain cerivastatin sodium medication worldwide (with the exception of the United States) under the trade name Lipobay. In the United States, the drug was marketed as Baycol. Bayer AG has sufficient contacts with the state of South Dakota for purposes of proper service and personal jurisdiction.

6. There existed and continues to exist a unity of interest in ownership between Bayer AG and Bayer Corporation such that any individuality and separateness between them has ceased and these Defendants are alter-egos of one another and exerted control over each other. At all times relevant herein, they shared officers and directors and made all decisions as one corporation, including, but not limited to, all decisions regarding the design, manufacture, testing, marketing and distribution of Baycol.

7. The Defendant Smith Kline Beecham Corporation, d/b/a GSK, is a Pennsylvania corporation.

JURISDICTION

8. The amount in controversy exceeds Seventy-five Thousand Dollars ($75,000), exclusive of costs and interest. Jurisdiction is conferred upon this Court pursuant to Title 28 U.S.C. § 1332.

DIVERSITY

9. That all of the Defendants are citizens of the state other than the state of South Dakota or are citizens of another country. That the Plaintiffs were and are residents of the state of South Dakota.

FACTUAL ALLEGATIONS AGAINST DEFENDANTS

10. At all times relevant hereto, the Defendants, themselves or by use of others, did research, develop, manufacture, create, design, test, label, sterilize, package, distribute, supply, market, sell, promote, advertise, warn and otherwise distribute in interstate commerce the above described pharmaceutical product Baycol.

11. Baycol belongs to a class of drugs called "statins" that are believed to lower LDL cholesterol and triglycerides by inhibiting a certain liver enzyme necessary for the production of cholesterol. Statins are commonly prescribed to generally lower cholesterol levels and potentially decreasing the risk for future heart disease.

12. Baycol is generally considered more potent than other statin drugs, in that it takes effect at a much lower dosage amounts than other statins. However, this trait does not make it more effective than the other statin drugs. Baycol is unlike other statins in the way it is metabolized in the liver.

13. The first wave of statins was approved by the FDA in the late 1980's and early 1990's: lovastatin (Mevacor®) in 1987 and pravastatin (Pravachol®) and simvastatin (Zocor®) in 1991. All three share closely related chemical structures. The second wave came with the approval of fluvastatin (Lescol®), and Baycol and atorvastatin (lipitor®) followed as the third wave in 1997.

14. In June 1997, the Bayer Defendants received approval from the United States Food and Drug Administration (the "FDA") to market Baycol in the United States at doses of 0.2 and 0.3 mg. The Bayer Defendants were aware that Baycol was less efficacious at the approved dosages than any other statin drugs already on the market. Indeed, the FDA specifically stated that the Bayer Defendants could not make the same efficacy claims for Baycol as compared to other marketed statins. Accordingly, in May 1999, the Bayer Defendants received FDA approval to market a 0.4 mg dose and later in July 2000 received further FDA approval to market a 0.8 mg dose.

15. Since statins had been on the market for so long, and because Baycol made no claims to the FDA of superiority to other statins, Baycol was approved after clinical trials involving only about 1,000 test subjects, far less than clinical studies concerning earlier statins marketed by others. Bayer did not prove through its clinical trial that use of Baycol reduced either the risk of coronary heart disease or deaths from heart disease.

16. The cholesterol-lowering drug market is significant, and the Defendants viewed Baycol as a major product with significant projected growth potential. Before its recall, Baycol was reported as having approximately 5% of the market share of cholesterol reducing drugs, and as being used by more than 700,000 patients in the United States.

17. The Defendants were aware that Baycol was less efficacious at the approved dosages than other statins on the market. Nevertheless, the Defendants marketed Baycol aggressively, claiming it was an "exciting new alternative treatment option" because of the "ultra-low doses needed to achieve cholesterol reduction."

18. In October 1999, the FDA's Division of Drug Marketing, Advertising and Communications set Bayer Corporation a letter informing it that dissemination of its promotional

material violated the Federal Food, Drug, and Cosmetic Act because it was "false, lacking in fair balance, or otherwise misleading." The letter criticizes a number of statements either directly claiming or implying that Baycol was superior to other statins. The letter also indicates "the presentation of risk information . . . lacks fair balance," and that "the most important risk information (risk of myopathy, rhabdomyolysis, etc.,) was hidden in this Sales Aid." Bayer was ordered to immediately cease using these promotional materials because of their misleading and inaccurate nature.

19. When Baycol entered the market, there were already several statins on the market that were just as effective, if not more so, in lowering cholesterol levels. In fact, two of the preexisting statins accounted for almost 75% of the market for statin drugs in the United States. The Defendants achieved their market share by selling Baycol at a price significantly lower than that of other statins, which influenced insurance companies and HMOs to place Baycol on their preferred drug lists.

20. At least as early as 1998, the Defendants first became aware that Baycol was linked to a fatality cause by rhabdomyolysis. Rhabdomyolysis is a very serious condition involving muscle deterioration. Essentially, when the skeletal muscle is damaged, an iron containing pigment found in the skeletal muscle called myoglobin is released into the bloodstream. The kidneys attempt to filter the myoglobin out of the bloodstream, but the myoglobin can block and occlude the structures within the kidney, resulting in damage, such as acute tubular necrosis or kidney failure. Additionally, the dead (necrotic) skeletal muscle can cause large fluid shifts from the bloodstream into the muscle, which reduces the relative fluid volume of the body and can lead to shock and reduced blocked flow to the kidneys and can ultimately lead to death.

21. Since the first reported fatality from Baycol induced rhabdomyolysis, there have been a total of 52 deaths reported which are associated with use of Baycol. Additionally, there are reported many cases of muscle weakness and/or damage associated with use of Baycol.

22. The permanent consequences of rhabdomyolysis can include muscle tissue degeneration, damage to the kidneys, liver lesions, damage to other major organs, including the heart, and death.

23. Given the high rate of adverse event reports associated with the ingestion of Baycol, the Defendants knew or should have known that a significant portion of the adverse effects experienced were causally related to Baycol use because they were the same experiences as had occurred in controlled studies. Studies of subjects taking Baycol reveal that a substantial number of patients show significant increased levels of enzymes which induce destruction of muscle cells. In addition, the studies showed that higher dosages of Baycol led to even higher levels in a greater number of test subjects.

24. Despite these clinical trials and the experience of patients, the Defendants persisted in seeking approval of higher dosages. As indicated above, the Bayer Defendants went back on two separate occasions to the FDA to seek approval of increased dosage amounts of 0.4 mg and 0.8mg respectively.

25. During the same time, the Defendants continued to receive notice and information of adverse events associated with Baycol, both directly from doctors and from the FDA. These adverse events occurred more frequently with the higher dosage levels. Since both Bayer Corporation and Bayer AG share officers and directors and since Bayer Corporation was co-marketing the drug with GlaxoSmithKline, Defendants were aware of the growing number of adverse events reported concerning use of Baycol.

26. Before its recall, Baycol was often jointly prescribed and administered with gemfibrozil (Lopid) to improve the balance of triglycerides and HDL, the "good cholesterol." In December 1999, Bayer Corporation changed the Baycol prescribing information to include a contraindication of use of Baycol with gemfibrozil. Further, on May 21, 2001, Bayer sent a "Dear Doctor" letter which belatedly called attention to some of the dangers associated with Baycol use, particularly when combined with gemfibrozil. Nevertheless, Bayer continued to misrepresent and conceal the dangers associated with Baycol. Still the company insisted, "When used as directed, Baycol effectively and safely treats patients with hyperlipidemia [high cholesterol levels]."

27. These warnings were insufficient because they were inadequate, untimely and not sufficient to prevent co-prescription of Baycol with gemfibrozil. Additionally, long before this "Dear Doctor" letter was sent, Baycol, taken alone, was associated with a significant number of adverse events in relation to its market share and this information was not sufficiently, adequately and timely provided to the medical community and to consumers.

28. Despite the Defendants' knowledge of the inadequacy of the warnings, and of the dose-dependent and inherent dangers of Baycol use, the Defendants continued to conceal the adverse effects associated with Baycol use and to market the drug throughout the United States and abroad.

29. Moreover, while the advertisements' statements of efficacy were large and prominent, the statements of risk and danger were embedded in lengthy fine print statements and were misleading in their content and presentation.

30. On August 8, 2001, Bayer announced it was withdrawing Baycol from the market for public safety reasons. At the same time, the Bayer Defendants finally revealed the dangers

associated with Baycol by issuing a letter to doctors, now stating "Rhabdomyolysis is a serious, potentially fatal, adverse effect of all statin drugs, including Baycol. It can occur with statin monotherapy, through the risk appears to be increased significantly by concomitant use of gemfibrozil (Lopid)."

31. The German Health Ministry accused Bayer AG of grave errors in its information policy regarding the side effects of Baycol. Bayer AG was charged with having withheld information on the side effects from the German Institute for Drugs and Medical Products for a period of time and only made the information available when requested to do so.

32. As previously asserted, Baycol has been strongly associated with causing rhabdomyolysis. One of the known symptoms of rhabdomyolysis is muscle pain. However, despite the Defendants knowledge that Baycol caused significant muscle cell destruction and release of myoglobin in the blood stream, patients were never told that symptoms of muscle pain might be indicative of an adverse reaction to Baycol. Additionally, patients and physicians were not advised to monitor their creatinine kinase (CK) levels. A significant increase in the CK levels is a strong indication of ongoing rhabdomyolysis.

33. The Defendants falsely and deceptively misrepresented or omitted a number of material facts concerning Baycol, including, but not limited to, adverse health effects caused by Baycol including the frequency, severity and rapid development of these adverse events.

34. Despite the Defendants knowledge that Baycol was harmful to health and often caused life threatening illnesses and death to patients, Defendants continued to promote and advertise Baycol to physicians and consumers.

35. Had Plaintiffs known of the full extent of the risks and dangers associated with Baycol, Plaintiff Erk would not have purchased or ingested Baycol.

36. The Defendants knew or should have known that Baycol created significant risks of serious injuries or disorders, including damage to kidneys, liver and heart, as to which the Defendants failed to adequately warn the public and physicians about the special risks and serious problems associated with the use of Baycol.

ALLEGATIONS REGARDING PLAINTIFF MARK ERK

37. Plaintiff Mark Erk was prescribed, purchased and ingested 0.3 mg of Baycol each day from September 11, 1998, until April 6, 1999, when the dosage was increased to 0.6 mg daily. On September 7, 1999, Plaintiff Mark Erk presented to the doctor with severe, diffuse body aches (muscles and joints) and weakness which had started approximately three days prior to September 7, 1999. He had discontinued the Baycol a couple of days before seeking medical treatment because of the severe muscles pain and weakness. CPK results were initially 400, but dramatically increased on September 9, 1999, to 3300. Erk's symptoms, all of which, unknown to Plaintiff Erk, were symptoms of rhabdomyolysis caused from the use of Baycol.

38. Neither Erk nor his doctor were aware of, nor had they been informed by Defendants, notwithstanding that said Defendants knew and were aware that Baycol was causing rhabdomyolysis and death to patients on the drug.

39. Defendants Bayer and GlaxoSmithKline, recalled Baycol on August 8, 2001.

40. Since the initial onset of symptoms, Plaintiff Erk has developed chronic myalgias and arthralgias to the point of frank arthropathy, which condition is permanent.

41. As a foreseeable, direct, substantial, and proximate cause and result of the negligence, carelessness, and unlawful conduct of the Defendants, Plaintiff Mark Erk has and will continue to have pain and suffering, mental and emotional distress, loss of

enjoyment of life, loss of income, loss of earning capacity in the future, current and future medical expenses, permanent physical impairment, and other damages, in an amount to be determined at trial and which exceeds the jurisdictional limits of this Court.

COUNT ONE
AGAINST BAYER DEFENDANTS
AND GLAXOSMITHKLINE DEFENDANTS

42. Plaintiffs adopt and incorporate all the allegations in the above paragraphs.

43. At all times material hereto, the Defendants have regularly engaged in the business of designing, testing, manufacturing, marketing, advertising, supplying, distributing, and selling Baycol that is defective and unreasonably dangerous.

44. At all times material hereto, Baycol was designed, tested, manufactured, marketed, advertised, supplied, distributed, and sold by the Defendants and was expected to reach, and did reach, consumers, including Plaintiff Erk, without substantial change in the condition in which it left the possession of the Defendants.

45. At all times material hereto, Baycol was defective and unreasonably dangerous because:

a. When placed in the stream of commerce, Baycol contained unreasonably dangerous defects and was not reasonably safe as intended to be used, subjecting Plaintiff Erk to risks which exceeded the benefits of the drug;

b. When placed in the stream of commerce, Baycol was defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect and more dangerous than risks associated with other statin drugs;

c. The drug was insufficiently and inadequately tested;

d. The drug was not accompanied by adequate instructions and warnings to fully apprise the user of the full nature and extent of the risks and the dangerous side effects associated with its use;

e. The drug increased the risk of rhabdomyolysis beyond those of other statin drugs;

f. The Baycol designed, manufactured, supplied or marketed by Defendants was not accompanied by proper and adequate warnings to physicians and the medical community regarding all possible adverse side effects associated with the use of Baycol and the comparative severity and duration of such adverse effects;

g. The warnings and information provided to the medical community regarding Baycol did not accurately reflect the symptoms, scope of severity of the potential side effects;

h. The Baycol designed, manufactured, supplied or marketed by Defendants was defective and unreasonably dangerous due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of injury and death from Baycol, Defendants failed to provide adequate warnings to physicians and the medical community, Defendants continued to aggressively promote the product.

46. As a direct and proximate result of the defective and unreasonably dangerous condition of Baycol, Plaintiff Erk has suffered serious and permanent physical injury, and has suffered great past and present pain, great mental and physical injury and physical pain; he has suffered and will suffer for the remainder of his life a permanent impairment which restricts him from participating in the normal activities of his life; he has suffered diminished capacity to enjoy life; he has incurred medical expenses and will continue in the future to incur medical expenses; and he has suffered loss of wages, loss of earning capacity, and economic loss.

COUNT TWO
FAILURE TO WARN AGAINST BAYER DEFENDANTS AND GLAXOSMITHKLINE DEFENDANTS

47. Plaintiffs adopt and incorporate all the allegations in the above paragraphs.

48. Baycol was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained inadequate and insufficient warnings to alert the medical community, physicians and consumers, of the dangerous risks and adverse reactions associated with Baycol, including developing rhabdomyolysis.

49. Moreover, the Defendants owed a duty to accurately and reasonably warn of adverse side effects as a result of taking Baycol. The Defendants were negligent and breached this duty by failing to sufficiently, properly and adequately warn the medical community, physicians and consumers, of the adverse side effects associated with the use of Baycol.

50. Plaintiff Erk used the Baycol drug for its intended purpose, i.e., as a cholesterol reducing medication.

51. Plaintiff Erk could not have discovered any defective and unreasonably dangerous condition of the drug through the exercise of reasonable care.

52. The Defendants, as designers, manufacturers and distributors of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and further, Defendants had knowledge or should have had knowledge of the dangerous risks and serious adverse side effects of Baycol.

53. Plaintiff Erk did not have the same knowledge as the Defendants and no adequate warning was communicated to Plaintiff Erk.

54. The Defendants had a continuing duty to warn the medical community, physicians and consumers, including Plaintiff Erk, of the adverse risks and dangers associated with use of Baycol, and by negligently and/or wantonly failing to adequately,

accurately and sufficiently warn of the dangers associated with the use of Baycol, Defendants breached its duty.

55. As a direct and proximate result of actions, lack of action and conduct of the Defendants, Plaintiff Erk suffered permanent injuries.

COUNT THREE
BREACH OF WARRANTY OF MERCHANTABILITY AGAINST DEFENDANTS

56. Plaintiffs adopt and incorporate all the allegations of the above paragraphs.

57. When the Defendants placed the Baycol into the stream of commerce, they knew that the drug would be used as a cholesterol lowering medication and expressly and impliedly warranted to Plaintiff Erk that the use of this medication was safe and effective for its intended purpose.

58. Plaintiff Erk reasonably relied upon the expertise, skill, judgment and knowledge of the Defendants and upon the express and/or implied warranty that Baycol was of merchantable quality and fit for its intended use as a cholesterol lowering drug.

59. Baycol was not of merchantable quality and was not safe or fit for its intended use because it was unfit for the ordinary purposes for which statin drugs are used, in that it causes injury and death. The Baycol drug breached the warranties because it was unduly dangerous in expected use and did cause undue injury to Plaintiff Erk.

60. As a direct and proximate result of actions and conduct of the Defendants, Plaintiff Erk suffered permanent injuries.

COUNT FOUR
NEGLIGENCE AND/OR WANTONNESS AGAINST BAYER DEFENDANTS AND THE GLAXOSMITHKLINE DEFENDANTS

61. Plaintiffs adopt and incorporate all the allegations of the above paragraphs.

62. The Defendants, at all times material hereto, had a duty to Plaintiff Erk to exercise reasonable care in the design, testing, manufacturing, advertising, marketing, labeling, packaging, distribution, promotion, and sale of Baycol.

63. Defendants negligently and/or wantonly designed, tested, manufactured, advertised, marketed, labeled, packaged, distributed, promoted and sold, in the state of South Dakota, the Baycol drug.

64. Defendants breached their duty and were negligent and/or wanton in their actions, misrepresentations, and omissions toward Plaintiff Erk in the following manner:

a. Failed to include or provide adequate and sufficient warnings with the drug that would alert Plaintiff Erk and other consumers, the medical community and physicians, of the potential risks and serious side effects of taking Baycol;

b. Failed to adequately and properly test Baycol before placing it on the market and once the product was on the market;

c. Failed to conduct sufficient and adequate testing on Baycol which, if properly performed, would have shown that Baycol had serious side effects, including, but not limited to, developing rhabdomyolysis;

d. Failed to adequately and properly warn Plaintiff Erk, the medical community and physicians that use of Baycol carried a risk of death due to rhabdomyolysis;

e. Failed to provide adequate and sufficient post-marketing warnings or instructions after Defendants knew or should have known of the significant risks and adverse side effects from taking Baycol;

f. Failed to use due care in designing and manufacturing Baycol so as to avoid the aforementioned risks to individuals when Baycol was prescribed;

g. Failed to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Baycol and failed to properly report the results of their clinical trials and studies;

h. Failed to timely apprise and inform the FDA of the new information concerning adverse events;

i. Delayed warning of and failed to provide adequate warning about adverse symptoms, thereby depriving medical providers of the ability to assess risks, advise and monitor patients and properly monitor, diagnose and treat adverse reactions in patients like and including Plaintiff Erk.

65. As a direct and proximate result of actions, inactions and conduct of the Defendants, Plaintiff Erk suffered permanent injuries.

COUNT FIVE
CLAIM OF PLAINTIFF CANDACE R. ERK

66. Plaintiffs adopt and incorporate all the allegations of the above paragraphs.

67. As a foreseeable, direct, substantial, and proximate cause and result of the negligence, carelessness, and unlawful conduct of the Defendants, the Plaintiff, Candace R. Erk Manthey, sustained economic and non-economic losses, the loss of enjoyment of life, including the loss of consortium, society and companionship with her husband, Mark Erk, in an amount to be determined at trial and which exceeds the jurisdictional limits of this Court.

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

1. For compensatory damages in an amount to be determined by the jury;

2. For their costs and disbursements herein;

3. For prejudgment and post-judgment interest;

4. For punitive and exemplary damages in an amount determined by the jury to be sufficient to punish and deter the Defendants for their willful, wanton and reckless conduct.

5. For such other and further relief as may be deemed proper by the Court.

Dated this 4th day of August, 2003.

GUNDERSON, PALMER, GOODSELL & NELSON

G. Verne Goodsell
Attorneys for Plaintiffs
P.O. Box 8045
Rapid City, SD 57709-8045
(605) 342-1078

and

GROVES LAW OFFICE
Wm. Jason Groves
P.O. Box 8417
Rapid City, SD 57709-8417
(605) 341-4747

PLAINTIFFS REQUEST TRIAL BY JURY ON ALL ISSUES

By: _____
G. Verne Goodsell